



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

November 9, 1999

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-14

Greg Giannulis, Owner
Mike's Quality Meats
12110 Business Boulevard
Eagle River, Alaska 99577

WARNING LETTER

Dear Mr. Giannulis:

On May 18, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 12110 Business Boulevard, Eagle River, Alaska. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. 21 CFR Part 123.16 requires processors of smoked seafood products to include in their HACCP plan how they are controlling the food safety hazard of *Clostridium botulinum* toxin formation for at least as long as the shelf life of the product under normal and moderate abuse conditions. By virtue of these deficiencies, the smoked fish products processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. You must have a HACCP plan that lists the critical control points necessary to reduce the hazard of *Clostridium botulinum* toxin formation to an acceptable level (21 CFR 123.6(c)(2)). However, your firm's HACCP plan for cold-smoked salmon does not list a critical control point at the drying step for this purpose. It is recommended that temperatures in the smoker not exceed 90°F or the beneficial acid-forming bacteria that help to preserve the cold-smoked product may be destroyed. In addition, there is no critical control point at the finished product storage step. Vacuum-packed fishery products must be maintained under refrigeration at or below 38°F (with other appropriate barriers such as water phase salt concentrations) or stored frozen as a barrier to *C. botulinum* growth and toxin formation.

2. You must have a HACCP plan that lists all the critical limits that must be met in order to reduce the hazard of *Clostridium botulinum* toxin to an acceptable level (21 CFR 123.6(c)(3)). However, your firm's HACCP plans for hot and cold-smoked salmon do not list critical limits of salt concentration in the brine and your HACCP plan for cold-smoked salmon does not list a critical limit for water phase salt in the final product. If you do not use nitrites to control *C. botulinum*, as was stated by Randy Phelps during our May 1998 inspection, your process parameters must result in water phase salt of 3.5% in the finished product.

You are required by 21 CFR 123.8(a) to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur in your refrigerated vacuum-packed smoked products. However, your firm did not verify that the critical limits at your brining, smoking and cooking critical control points, for both cold and hot smoking processes, result in a minimum water phase salt concentration of 3.5% in the fish flesh. FDA found 5 out of 10 subsamples of hot-smoked, vacuum-packaged halibut had less than 3.5% water phase salt.

3. Your HACCP plan for hot and cold smoked, vacuum packaged salmon, states [REDACTED] ppm as your critical limit for the brine solution.

This critical limit is not adequate as defined by 21 CFR Part 123.3(c). 21 CFR Part 123.8(a) requires you to verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

During the previous inspection, on May 6-9 and 11, 1998, and in a letter from the FDA, dated June 22, 1998, you were notified of the same deficiencies described in point number one of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct these deficiencies. The FDA is concerned that in eleven months time your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action

Greg Giannulis, Owner
Mike's Quality Meats, Eagle River, AK
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cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Celeste M. Corcoran

for Austin R. Long, Ph.D.
Acting District Director

Enclosures:

FORM FDA 483

21 CFR Part 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
ADEC